

REMARKS

In response to the above-identified Office Action (“Action”), Applicants traverse the Examiner’s rejection to the claims and seek reconsideration thereof. Claims 1, 3-14, 32 and 38-54 are pending in the present application. Claims 1, 3-14, 32 and 38-54 are rejected and claims 48 and 53 are objected to. In this response, claims 1, 38, 48, 49 and 53 are amended, no claims are cancelled and claim 55 is added.

I. Claim Amendments

Applicants respectfully submit herewith amendments to claims 1, 38, 48, 49 and 53 and new claim 55. Claim 1 is amended to recite that the identifying comprises “identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging.” Support for the amendments to claim 1 may be found, for example, at page 29, ¶[0090] and page 30, ¶[0091] of the Application. Claim 38 is amended to recite the element of “directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device.” Support for the amendments to claim 38 may be found, for example, at page 30, ¶[0091] of the Application. Claims 48, 49 and 53 are amended to correct typographical errors. Support for new claim 55 may be found, for example, at page 29, ¶[0090] of the Application.

Applicants respectfully submit the amendments do not add new matter and are supported by the specification. Accordingly, Applicants respectfully request consideration and entry of the amendments to claims 1, 38, 48, 49 and 53 and new claim 55.

II. Claim Objections

In the outstanding Action, claims 48 and 53 are objected to due to informalities. Applicants respectfully submit the above amendments to claims 48 and 53 in which the typographical errors noted by the Examiner are corrected.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the above-referenced claim objections to claims 48 and 53.

III. Claim Rejections – 35 U.S.C. §102

In the outstanding Action, claims 1, 3, 5-9, 12, 14, 38-40, 48 and 53 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,602,241 issued to Makower, et al. (“Makower”).

It is axiomatic to a finding of anticipation that each and every element of the rejected claim be found within a single prior art reference.

Independent claim 1 recites:

1. A method comprising:
positioning a distal portion of a delivery device at a location in a blood vessel;
imaging a thickness of at least a portion of a wall of the blood vessel at the location with an imaging assembly disposed in a lumen of the delivery device;
identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging;
advancing a first portion of the distal portion of the delivery device a distance into the wall of the blood vessel to the treatment site beyond the external elastic lamina of the blood vessel; and
after advancing the first portion of the delivery device, introducing a treatment agent in a sustained release composition through the first portion of the delivery device.

Independent claim 38 recites:

1. A method comprising:
positioning a distal portion of a delivery device at a location in a blood vessel;
imaging a thickness of at least a portion of a wall of the blood vessel at the location with an imaging assembly disposed in a lumen of the delivery device;
directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device;
advancing a first portion of the distal portion of the delivery device a distance into the wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and
after advancing the first portion of the delivery device, introducing a treatment agent through the first portion of the delivery device,
wherein the treatment agent comprises an inflammation-inducing agent.

In regard to independent claim 1, Applicants respectfully submit that Makower fails to teach at least the elements of “identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging” as recited in amended claim 1.

The Patent Office alleges that Makower discloses a method of delivering substances to extravascular treatment sites including advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment site. The Patent Office alleges that Makower further discloses that after imaging, the catheter is advanced through the vessel wall to deliver a treatment agent to the target site, including a sustained release treatment agent and/or inflammation inducing agent. Apparently recognizing the failure of Makower to disclose imaging a thickness of the vessel wall, the Patent Office alleges that this feature would be inherently provided by the imaging step disclosed in Makower. See Action, page 2.

As acknowledged by the Patent Office, Makower does not describe imaging of a thickness of the vessel wall. Rather, Makower discloses the use of a guidance element for “the positioning and rotational orientation of the catheter 11 within the vasculature such that the vessel wall penetrator 85 will be properly aimed in the direction of the target site.” See Makower, col. 8, lines 20-25. Makower further discloses that the guidance element may include an imaging transducer that “emits ultrasound signals and receives back echos or reflections which are representative of the nature of the surrounding environment.” See Makower, col. 8, lines 40-45. Thus, Makower clearly discloses that the information obtained from the guidance element relates to the structure of the vessel wall surrounding the catheter, not the structure beyond the vessel wall, so that the penetrator 85 can be aimed at the desired wall region. Imaging of a thickness of the vessel wall is neither relevant nor considered by Makower to properly direct penetrator 85. Accordingly, any inherent imaging of the thickness of the vessel wall that may occur using the guidance element of Makower is not used to identify a treatment site beyond an external elastic lamina of the blood vessel as required by amended claim 1.

In regard to independent claim 38, Applicants respectfully submit that Makower fails to teach at least the elements of “directing the distal portion of the delivery device toward the

portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device” as recited in amended claim 38. Rather, Makower discloses a vessel wall penetrating catheter 11 including a vessel wall penetrator 85 and delivery catheter 12 that may be advanced out of the vessel wall penetrator 85 into the tissue. The vessel wall penetrating catheter 11 of Makower does not include a balloon, much less a balloon for directing the distal portion of the delivery device toward the portion of the vessel wall by inflating the balloon as required by claim 38.

Since Makower fails to teach each and every element of independent claims 1 and 38, claims 1 and 38 are not anticipated by the cited prior art reference. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 38 under 35 U.S.C. §102 over Makower.

In regard to claims 3, 5-9, 12, 14, 39-40, 48 and 53, these claims depend from claims 1 and 38 and incorporate the limitations thereof. Thus, for at least the reasons that claims 1 and 38 are not anticipated by Makower, claims 3, 5-9, 12, 14, 39-40, 48 and 53 are further not anticipated by the cited prior art reference. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 3, 5-9, 12, 14, 39-40, 48 and 53 under 35 U.S.C. §102 over Makower.

IV. Claims Rejections – 35 U.S.C. § 103

A. In the Action, claims 4, 32 and 54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent No. 6,514,217 issued to Selmon, et al. (“Selmon”).

To establish a *prima facie* case of obviousness, the Examiner must set forth “some articulated reasoning with some rational underpinning to support the conclusion of obviousness.” See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). In combining prior art elements to render the claimed combination of elements obvious, the Examiner must show that the results would have been predictable to one of ordinary skill in the art. See *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103*, Section III(D), issued by the U.S. Patent and Trademark Office on October 10, 2007.

In regard to claims 4, 32 and 54, these claims depend from claims 1 or 38 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of “identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging” and “directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device” as incorporated into claims 4, 32 and 54 from claims 1 or 38. Selmon further fails to cure the deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claims 4, 32 and 54 are not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4, 32 and 54 under 35 U.S.C. §103 over Makower and Selmon.

B. In the Action, claims 7-8, 10-13, 41-43, 46-47 and 51-52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower.

In regard to claims 7-8, 10-13, 41-43, 46-47 and 51-52, these claims depend from claims 1 or 38 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of “identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging” and “directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device” as incorporated into claims 7-8, 10-13, 41-43, 46-47 and 51-52 from claims 1 or 38. Thus, for at least the reasons previously discussed, claims 7-8, 10-13, 41-43, 46-47 and 51-52 are further not obvious over the cited prior art reference. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 7-8, 10-13, 41-43, 46-47 and 51-52 under 35 U.S.C. §103 over Makower.

C. In the Action, claims 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent Publication No. 2002/0131974 of Segal (“Segal”).

In regard to claim 11, this claim depends from claim 1 and incorporates the limitations thereof. For at least the reasons previously discussed, Makower does not disclose the limitations of “identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging” as incorporated into claim 11 from claim 1. Segal does not cure these deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claim 11 is not

obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. §103 over Makower and Segal.

D. In the Action, claims 12-13, 41-43, 47 and 52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent No. 5,749,915 issued to Slepian (“Slepian”).

In regard to claims 12-13, 41-43, 47 and 52, these claims depend from claims 1 or 38 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of “identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging” and “directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device” as incorporated into claims 12-13, 41-43, 47 and 52 from claims 1 or 38. Slepian does not cure the deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claims 12-13, 41-43, 47 and 52 are not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 12-13, 41-43, 47 and 52 under 35 U.S.C. §103 over Makower and Slepian.

E. In the Action, claims 44-45 and 49-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent No. 5,676,151 issued to Yock (“Yock”) or U.S. Patent No. 6,338,717 issued to Ouchi (“Ouchi”).

In regard to claims 44-45 and 49-50, these claims depend from claims 1 or 38 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of “identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging” and “directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device” as incorporated into claims 44-45 and 49-50 from claims 1 or 38. Neither Yock nor Ouchi cure the deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claims 44-45 and 49-50 are further not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 44-45 and 49-50 under 35 U.S.C. §103 over Makower and Yock or Ouchi.

IV. Claim Rejections – 35 U.S.C. §102

New claim 55 depends from claim 1 and incorporates the limitations therefore. Thus, for at least the reasons that claim 1 is not anticipated by, or prima facie obvious in view of, the cited prior art references, claim 55 is further patentable over the art of record. Claim 55 is further patentable for at least the reasons that the prior art of record fails to disclose the additional elements of “measuring the thickness of the portion of the wall of the blood vessel using the imaging assembly; and identifying the treatment site based on the imaging and measuring” as recited in claim 55.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 1, 3-14, 32 and 38-54, are now in condition for allowance and such action is earnestly solicited at the earliest possible date. If there are any additional fees due in connection with the filing of this response, please charge those fees to our Deposit Account No. 02-2666. Questions regarding this matter should be directed to the undersigned at (310) 207-3800.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

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By: 
Stacie J. Sundquist, Reg. No. 53,654

1279 Oakmead Parkway
Sunnyvale, California 94085-4040
Telephone (310) 207-3800
Facsimile (408) 720-8383

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.


Susan M. Manriquez

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